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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/246,129	02/08/99	YU G	PF141P4

HM22/0929

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

EXAMINER	
DRAPER, T	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES DEPARTMENT OF COMMERCE
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DATE MAILED:

Jar Restriction and Sequence Compliance

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-41 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-41 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

1. Part III: Detailed Office Action For Restriction and Sequence Compliance

2. First of all it is pointed out that no attempt was made to require a telephone election because each in of the parent applications, applicants have request a written restriction requirement. Furthermore, this is generally the case for many other applications by the Assignee, HGS that are examined by Examiner Draper.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to nucleic acids encoding TNF-gamma-α vectors, host cells, and methods of making the vector, host cells and the encoded protein, classified in classes 435 and 536, subclasses 69.5+ and 23.5 respectively .

II. Claim 17, drawn to TNF-gamma-α, classified in class 530, subclass 351.

III. Claim 18, drawn to antibody to the TNF-gamma-α, classified in class 530, subclass 388.23.

IV. Claims 19-20, drawn to methods of treating tumors with the nucleic acid that encodes the TNF-gamma-α, classified in class 514, subclass 44.

V. Claim 21, drawn to methods of treating Rheumatoid Arthritis with the TNF-gamma-α protein, classified in class 424, subclass 85.1.

VI. Claims 22-36, drawn to nucleic acids encoding TNF-gamma-β vectors, host cells, and methods of making the vector, host cells and the encoded protein, classified in classes 435 and 536, subclasses 69.5+ and 23.5 respectively .

VII. Claim 37, drawn to TNF-gamma-β, classified in class 530, subclass 351.

VIII. Claim 38, drawn to antibody to the TNF-gamma-β, classified in class 530, subclass 388.23.

IX. Claims 39-40, drawn to methods of treating tumors with the nucleic acid that encodes the TNF-gamma-β, classified in class 514, subclass 44.

X. Claim 41, drawn to methods of treating Rheumatoid Arthritis with the TNF-gamma-β protein, classified 424, subclass 85.1.

The inventions are distinct, each from the other because:

Inventions Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be made by a materially different process such as by chemical synthesis, or it could be obtained from nature using the various isolation and chromatographic processes. Furthermore, these two groups contain products that are structurally, physically and functionally distinct, and if determined to be patentable, they are also patentably distinct.

Inventions Group I and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids and be used other than in gene therapy, such as to make the encoded protein, or it could be used to make transgenic animals, or it could be used as a probe. Furthermore, the methods of Group I are not required for the methods of Group IV and they use different step and have different outcomes.

Inventions Group II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein and be used other than to treat tumors, such as to make the antibodies, or it could be used to treat other therapeutic disorders, or it could be used in various diagnostic methods.

Inventions Group VI and Group VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be made by a materially different process such as by chemical synthesis, or it could be obtained from nature using the various isolation and chromatographic processes. Furthermore, these two groups contain products that are structurally, physically and functionally distinct, and if determined to be patentable, they are also patentably distinct.

Inventions Group VI and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids and be used other than in gene therapy, such as to make the encoded protein, or it could be used to make transgenic animals, or it could be used as a probe. Furthermore, the methods of Group VI are not required for the methods of Group IX and they use different step and have different outcomes.

Inventions Group VII and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein and be used other than to treat tumors, such as to make the antibodies, or it could be used to treat other therapeutic disorders, or it could be used in various diagnostic methods.

It is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different products, restriction is deemed to be proper because the products appear to constitute patentably distinct inventions. The inventive products of Groups I, II, III, VI, VII, and VIII are directed to products that are

structurally, physically and functionally distinct and if determined to be patentable they would also be patentably distinct. Furthermore, these products are not required one for the other, nor is each of the products used in each of the methods. And in a similar manner, each of the TNF-gamma-α products are not required for each of the TNF-gamma-β products or their methods.

In a similar manner it is further pointed out that although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for multiple/different methods, restriction is deemed to be proper because the methods appear to constitute patentably distinct inventions. The inventive methods of Groups I, VI, IV--->V, and IX---->X require the use of different steps/methods; elements/agents that are physically and functionally distinct; there are different starting elements and the final outcome/results are different for these different methods that cover various diagnostics and therapeutic methods; and if determined to be patentable they would also be patentably distinct. Furthermore, these methods are not required one for the other, nor does each of the methods require the use of each of the products. And in a similar manner, each of the TNF-gamma-α products are not required for each of the TNF-gamma-β products or their methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications which are not co-extensive. And there are different issues for the search and examination of each group, which would be unduly burdensome, accordingly, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Sequence Compliance:

The reply filed 8/98 and 11/98 is not fully responsive to the communication mailed 9/98 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report.

Since the above-mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS**, from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME LIMIT MAY BE GRANTED UNDER 37 CFR 1.136(a).

SEE THE ATTACHED ERROR REPORTS.

4. Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to **Garnette D. Draper, Art Unit 1646, whose telephone number is (703) 308-4232.** Examiner Draper can normally be reached Monday through Friday, 9:30 A.M. to 6:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Official papers filed by fax for this "Pilot for Written Restrictions" should be directed to (703) 305-3704-which is a Fax machine specifically for this pilot. Papers related to this application for election from the written restriction may be submitted to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

GARNETTE D. DRAPER
PRIMARY EXAMINER
GROUP 1800